UNITED STATES DEPARTMENT OF COMMERCE

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

18M1/0121 .

MCGREGOR & ADLER 8011 CANDLE LANE HOUSTON TX 77071

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	: .	DATE MAILED
08/774,154	12/26/96	009	SUN-HOFFMAN, L	1806	01/21/98
First Named ULLRICH, Applicant		итсо	L.E.		

TILE OF NOVEL METHOD OF DIAGNOSING AND TREATING GLIOMA

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ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPL	N. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 D5858	435-00	07.230	W57	UTILITY	YES	\$660.00	04/21/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED.</u>

HOW TO RESPOND TO THIS NOTICE:

- Review the SMALL ENTITY status shown above.
 If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

 Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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MCGREGOR & ADLER

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HOUSTON TX 77071

FILING DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NO.

08/774,154

12/26/96

ULLRICH

N D5858

18M1/0121

EXAMINER

SUN-HOFFMAN, L ART UNIT

PAPER NUMBER

1806

DATE MAILED:

01/21/98

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.
This communication is responsive to the telephone interview of 1/15/93.
The allowed claim(s) is/are 5-13
☐ The drawings filed on are acceptable.
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
received.
received in Application No. (Series Code/Serial Number)
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
Applicant MUST submit NEW FORMAL DRAWINGS
because the originally filed drawings were declared by applicant to be informal.
including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached herete ar to Paper No. 3.
including changes required by the proposed drawing correction filed on, which has been approved by the examiner.
including changes required by the attached Examiner's Amendment/Comment.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.
☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.
Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.
Attachment(s)
☐ Notice of References Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
Notice of Informal Patent Application, PTO-152
Interview Summary, PTO-413
🗹 Examiner's Amendment/Comment
Examiner's Comment Regarding Requirement for Deposit of Biological Material
Examiner's Statement of Reasons for Allowance

Serial Number: 08/774,154

Art Unit: 1806

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Benjamin Adler on January 15, 1998.

The application has been amended as follows,

Canceled non-elected claims 1-4 and 14-20.

Amended claims 5 and 7 as follows:

contacting a tissue of interest with an antibody that specifically recognizes an antigen [in]

specific to chloride channels of glial- or meningioma-derived tumor cells; and

measuring the level of binding of the antibody, wherein an elevated [a high] level of binding, relative to normal tissue, is indicative that the tissue is neoplastic.---

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Serial Number: 08/774,154

Art Unit: 1806

(Amended) A method of differentiating glial-derived or meningioma-derived neoplastic tumor tissue from non-neoplastic tissue, comprising the steps of:

contacting a tissue of interest with labeled chlorotoxin which binds specifically to glial or meningioma-derived neoplastic tumor tissue; and

measuring the level of binding of the labeled chlorotoxin, wherein <u>an elevated</u> [a high] level of binding, relative to normal tissue, is indicative that the tissue is neoplastic.---

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The prior art recognizes a correlation between elevated levels of chloride channels and neoplastic transformation, however, the instant invention is directed to a previously unknown glioma- and meningioma-specific chloride channel. Therefore, the instant invention, which is directed to the detection of glial- or meningioma-derived tumors through detection of elevated levels of the novel chloride channel is neither taught nor suggested in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



Serial Number: 08/774,154

Art Unit: 1806

COMMENT AND CONCLUSION

The Transmittal Sheet filed December 26, 1996 indicates that "This non-provisional application claims benefit of provisional application Serial No. 60/009,283 filed on December 27, 1995." However, the Transmittal Sheet was not accompanied by an amendment to the specification, nor is the provisional application mentioned in the oath for this non-provisional application. If the claim for priority is to appear on the face of the issued patent, a new oath referring to the provisional application is required, as is an amendment to the specification outlining the continuing information.

The following references are considered relevant to applicants' disclosure, and are made of record but not relied upon: Ullrich et al. (Am. J. Physiol., vol. 270, no. 5, pt. 1, pp. C1511-1521, 1996) discuss the biophysical and pharmacological characterization of chloride currents in human astrocytoma cells; Ullrich et al. (NeuroReport, vol. 7, no. 5, pp. 1020-1024) disclose expression of an anion current with unique properties that selectively characterizes brain tumor derived cells of glial origin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman whose telephone number is (703) 308-7552.

January 20, 1998

Doni R. Schuner